UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, Plaintiff, v. PHILIPS RS NORTH AMERICA LLC, RESPIRONICS CALIFORNIA LLC, and PHILIPS HOLDING USA INC., corporations, and ROY JAKOBS, STEVEN B. C DE BACA, THOMAS FALLON, DANIEL LEONARD, and JEFF DILULLO, individuals, Defendants.	No. 2:24-cv-505 COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, brings this action under the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 332(a), and alleges as follows:

INTRODUCTION

1. The United States seeks a statutory injunction pursuant to 21 U.S.C. § 332(a) to restrain Philips RS North America LLC, Respironics California LLC, and Philips Holding USA Inc. (collectively, "Philips"), and Roy Jakobs, Steven B. C de Baca, Thomas Fallon, Daniel Leonard, and Jeff DiLullo, individuals (collectively with Philips, "Defendants"), from:

a. Violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce or causing the introduction or delivery for introduction into interstate commerce, medical devices, within the meaning of 21 U.S.C. § 321(h), that are (1) adulterated within the meaning of 21 U.S.C. § 351(h), in that the methods used in, and the facilities and controls used for, their manufacture, packing, storage, and installation are not in conformity with

the current good manufacturing practice ("CGMP") requirements for devices, *see* 21 U.S.C. § 360j(f) and 21 C.F.R. Part 820; and/or (2) misbranded within the meaning of 21 U.S.C. § 352(t), in that Defendants fail to furnish material or information respecting their devices, as set forth in 21 U.S.C. § 360i(g) and 21 C.F.R. Part 806; and

b. Violating 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(h) and/or misbranded within the meaning of 21 U.S.C. § 352(t), while such devices are held for sale after shipment of one or more of their components in interstate commerce.

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1345, and 21 U.S.C. § 332(a), and has personal jurisdiction over all parties.

3. Venue in this Court is proper pursuant to 28 U.S.C. § 1391(b) and (c).

DEFENDANTS AND THEIR DEVICES

4. Philips RS North America LLC ("Philips Respironics") is a Delaware corporation located at 6501 Living Place, Pittsburgh, PA. Philips Respironics is a subsidiary of Philips RS North America Holding Corporation, which is a subsidiary of Philips Holding USA Inc. Philips Respironics designs, manufactures, and/or distributes articles of device, within the meaning of 21 U.S.C. § 321(h), at or from various facilities, including facilities located at 1001 and 1010 Murry Ridge Lane, Murrysville, PA; 312 Alvin Drive, New Kensington, PA; and 174 Tech Center Drive, Mount Pleasant, PA.

5. Respironics California LLC ("Respironics California"), a California corporation, is a subsidiary of Philips Respironics. Respironics California previously manufactured articles of device at its facility at 2271 Cosmos Court, Carlsbad, CA.

6. Philips Holding USA Inc. ("PHUSA"), a Delaware corporation, is located at 222 Jacobs Street, Cambridge, MA. PHUSA is a subsidiary of Koninklijke Philips N.V. ("Royal Philips"), a Dutch corporation. Royal Philips divides its medical device business into four different business segments: Connected Care, Diagnosis & Treatment, Personal Health, and Other. Each of these business segments is divided into units. Philips Respironics is part of the Sleep & Respiratory Care ("SRC") business unit of Royal Philips' Connected Care business segment. Respironics California is also part of the Connected Care business segment.

7. Roy Jakobs has served as the Chief Executive Officer for Royal Philips since October 15, 2022. The Chief Patient Safety & Quality Officer for Royal Philips reports directly to him. From February 2020 to October 15, 2022, Mr. Jakobs served as the Chief Business Leader for the Connected Care business segment. He performs his duties at Philips Center, Amstelplein 2, 1096 BC Amsterdam, the Netherlands.

8. Steven B. C de Baca is the Chief Patient Safety & Quality Officer for Royal Philips. He has held this position since February 6, 2023. He reports directly to Mr. Jakobs. He performs his duties at the PHUSA Cambridge, MA facility.

9. Thomas Fallon is employed by Philips Respironics and serves as the Head of Quality for the SRC business unit of the Connected Care business segment. He is responsible for quality at the SRC sites, including the Murrysville, New Kensington, and Mount Pleasant facilities, and he oversees Philips' remediation efforts related to recalls of devices manufactured at those facilities. He performs his duties at Philips Respironics' Pittsburgh, PA office.

10. Daniel Leonard is the President and CEO of Philips Respironics and Respironics California. He is also the Business Leader for the SRC business unit of the Connected Care business segment. He has held those positions since March 6, 2024. From January 22, 2024 to March 6, 2024, he served as the *ad interim* Business Leader for the SRC business unit. He performs his duties at the PHUSA Cambridge, MA facility.

11. Jeff DiLullo is the CEO and President of PHUSA. He has held this position since March 15, 2023. He performs his duties at the PHUSA Cambridge, MA facility.

12. Philips Respironics manufactures, among other things, continuous positive airway pressure ("CPAP") machines, bi-level positive airway pressure ("BiPAP") machines, and mechanical ventilators, which are devices within the meaning of 21 U.S.C. § 321(h). Philips Respironics manufactures devices at its Murrysville and New Kensington facilities using components that have been shipped in interstate commerce from locations outside of Pennsylvania. Philips Respironics distributes its devices in interstate commerce.

13. Philips Respironics initiated a voluntary recall notification for certain CPAP machines, BiPAP machines, and mechanical ventilators on June 14, 2021 ("June 2021 Recalls") due to potential health risks. The affected devices were manufactured at the Murrysville and New Kensington facilities and contain polyester-based polyurethane ("PE-PUR") foam, which was used for sound abatement. According to the recall notices issued at that time, the PE-PUR sound abatement foam "may degrade into particles which may enter the device's air pathway and be ingested or inhaled by the user," and "the PE-PUR foam may off-gas certain chemicals." *See* URGENT: Medical Device Recall, Philips Respironics, Trilogy 100, Trilogy 200, Garbin Plus, Aeris, LifeVent, BiPAP V30, and BiPAP A30/A40 Series Device Models, and URGENT: Medical Device Recall, Philips Respironics, CPAP and Bi-Level PAP Devices, both available at

https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/philips-recall-letter-2021-05-a-2021-06-a.pdf.

14. The United States Food and Drug Administration ("FDA" or "agency") classified the June 2021 Recalls as Class I. A recall is classified as Class I where there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death. *See* 21 C.F.R. § 7.3(m)(1).

15. The June 2021 Recalls involved millions of devices, and Philips Respironics' efforts to remediate those devices are ongoing. Some of the remediated devices have themselves been the subject of additional recalls. *See, e.g.*, Philips, URGENT Medical Device Recall Trilogy 100 and Trilogy 200 Silicone Abatement Foam Delamination, available at https://www.philips.com/c-dam/b2bhc/master/landing-pages/src/update/documents/en_US/trilogy/trilogy-field-safety-notice-en-us.pdf.

16. Respironics California manufactured mechanical ventilators for facility and home use, which are devices within the meaning of 21 U.S.C. § 321(h). These devices were manufactured at its facility in Carlsbad, CA, using components that were shipped in interstate commerce from locations outside of California, and the devices were distributed in interstate commerce. Respironics California ceased manufacturing devices at the Carlsbad facility on or before December 31, 2022, and has withdrawn the FDA establishment registration for that facility.

LEGAL STANDARDS

17. The Act authorizes FDA to "prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, pre-production design validation . . ., packing, storage, and installation of a device conform to current good manufacturing practice, as

prescribed in such regulations, to assure that the device will be safe and effective and otherwise in compliance with this [Act]." 21 U.S.C. § 360j(f)(1)(A). Pursuant to 21 U.S.C. § 360j(f), FDA has issued regulations setting forth CGMP requirements for devices in the Quality System Regulation, 21 C.F.R. Part 820 (hereafter, "QS regulation"). 21 C.F.R. § 820.1(a).

18. The failure to comply with any applicable QS regulation renders a device adulterated under 21 U.S.C. § 351(h). *See* 21 C.F.R. § 820.1(c).

19. The Act authorizes FDA to issue regulations requiring "a manufacturer . . . of a device to report promptly to the [agency] any correction or removal of a device undertaken by such manufacturer . . . if the removal or correction was undertaken (A) to reduce a risk to health posed by the device, or (B) to remedy a violation of [the Act] caused by the device which may present a risk to health." 21 U.S.C. § 360i(g). Pursuant to 21 U.S.C. § 360i(g), FDA has issued regulations setting forth requirements for reporting corrections and removals to FDA, 21 C.F.R. Part 806 (hereinafter "RCR regulation"). 21 C.F.R. § 806.1.

20. The failure to comply with the RCR regulation renders a device misbranded under 21 U.S.C. § 352(t)(2).

21. It is a violation of the Act to introduce or deliver for introduction into interstate commerce an adulterated or misbranded device. 21 U.S.C. § 331(a). It is also a violation of the Act to do any act with respect to a device that causes the device to become adulterated or misbranded while it is held for sale after shipment of one or more of its components in interstate commerce. 21 U.S.C. § 331(k).

DEFENDANTS' HISTORY OF VIOLATIONS

22. FDA inspected Philips Respironics' Murrysville, PA facility between August 26, 2021 and November 9, 2021. During the inspection, the FDA investigator documented

numerous significant violations of the Act and the QS regulation, including, but not limited to, the following:

a. Failure to establish and maintain adequate procedures for implementing corrective and preventive actions ("CAPA"), as required by 21 C.F.R. § 820.100(a).

b. Failure to establish and maintain design validation procedures to ensure that devices conform to defined user needs and intended uses, and include testing of production units under actual or simulated use conditions, as required by 21 C.F.R. § 820.30(g).

c. Failure to adequately establish procedures for identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation, as required by 21 C.F.R. § 820.30(i).

d. Failure to establish and maintain procedures to ensure that all purchased or otherwise received products and services conform to specified requirements, as required by 21 C.F.R. § 820.50.

23. During the inspection of the Murrysville facility, the FDA investigator also documented Philips Respironics' failure to submit written reports to FDA of corrections or removals of a device initiated by the manufacturer, as required by the RCR regulation, 21 C.F.R. § 806.10.

24. The Murrysville facility and the New Kensington facility share the same quality system.

25. At the close of the Murrysville inspection, FDA issued a list of inspection observations (Form FDA 483) describing the violations observed during the inspection. Philips Respironics responded to the inspection observations by letter dated December 9, 2021, and it has also submitted periodic updates to that response. In its December 9, 2021 letter, Philips

Respironics emphasized that it "takes FDA's observations seriously" and "is taking action to fully address the observations …." Some of the commitments described in Philips Respironics' response remain "in process," and FDA has not yet verified whether the reportedly completed actions are effective.

26. FDA inspected Philips Respironics' Mount Pleasant, PA facility between January 25, 2023 and February 14, 2023. Philips Respironics had performed remediation work on the recalled Trilogy 100 and 200 ventilators at the Mount Pleasant facility by removing the PE-PUR sound abatement foam in field-returned devices and replacing it with silicone foam. In July 2022, Philips Respironics began to receive complaints involving reworked Trilogy 100 and 200 ventilators that documented the presence of residual foam degradation particulates of PE-PUR foam in the airpath assembly. On September 30, 2022, Philips Respironics stopped its remediation of the Trilogy 100 and 200 ventilators and initiated a voluntary field action. During the 2023 inspection, regarding the firm's remediation process for the Trilogy 100 and 200 ventilators, the FDA investigator documented Philips Respironics' failure to validate with a high degree of assurance and approve according to established procedures a process whose results cannot be fully verified by subsequent inspection and test, as required by 21 C.F.R. § 820.75(a).

27. At the close of the inspection, FDA issued a list of inspection observations (Form FDA 483) describing the violation observed during the inspection. Philips Respironics responded by letter dated March 8, 2023, stating that it had "investigated" to "identify the root cause(s)" of the observation and "is taking action to fully address" it. FDA has not yet verified whether the firm's reportedly completed corrective actions are effective.

28. FDA previously sent two Warning Letters to Philips Respironics regarding the Murrysville, PA facility.

a. The first Warning Letter, dated October 11, 2011, pertained to the findings of a June 2011 inspection of the Murrysville facility during which FDA investigators documented Philips Respironics' failure to submit medical device reports ("MDRs") related to malfunctions of its Trilogy ventilators and its failure to establish adequate MDR procedures, as required by 21 C.F.R. Part 803. The Warning Letter explained that, due to these violations, the Trilogy ventilators were misbranded within the meaning of 21 U.S.C. § 352(t)(2).

b. The second Warning Letter, dated June 30, 2014, pertained to the findings of an April 2014 inspection of the Murrysville facility. Similar to the 2021 inspection, the 2014 inspection documented Philips Respironics' failure to ensure that all purchased or otherwise received products and services conform to specified requirements, as required by 21 C.F.R. § 820.50. It also documented Philips Respironics' failure to develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications, as required by 21 C.F.R. § 820.70.

c. Both Warning Letters stated that the letters were "not intended to be an all-inclusive list of the violations at" the facility and that it is the firm's "responsibility to ensure compliance with applicable laws and regulations . . . ." The Warning Letters also advised that failure to promptly correct the violations addressed in the letters may result in regulatory action being initiated by FDA without further notice, including, but not limited to, seizure, injunction, and civil money penalties.

29. FDA also previously documented significant CGMP violations related to the manufacture of V60 ventilators at Respironics California's Carlsbad, CA facility, which has since withdrawn its establishment registration.

a. During an inspection conducted between April 4, 2018 and May 21, 2018, an FDA investigator documented that Respironics California had failed to submit MDRs within the required timeframe specified in 21 C.F.R. Part 803 and that its procedures for design change were not adequately established. On March 1, 2019, FDA held a regulatory meeting with representatives from the firm to discuss the firm's corrective actions.

b. During a follow-up inspection conducted between December 10, 2019 and January 10, 2020, FDA investigators observed that some MDRs still were not being submitted within the required timeframe. The investigators also documented CGMP violations related to CAPA procedures, procedures for acceptance of incoming products, control of non-conforming product, and complaints.

c. On April 16, 2021, FDA sent a letter to Respironics California requesting a regulatory meeting to discuss the December 2019-January 2020 inspection findings and the firm's corrective actions. That meeting was held on June 30, 2021.

d. FDA subsequently documented CGMP violations during inspections in 2021 and 2022. Specifically, during an inspection conducted between August 30, 2021 and September 10, 2021, an FDA investigator documented CGMP violations related to design validation procedures and investigation of complaints. And, during an inspection conducted between April 25, 2022 and May 19, 2022, FDA investigators documented CGMP violations related to CAPA procedures and document control procedures.

e. Respironics California ceased manufacturing devices at the Carlsbad facility on or before December 31, 2022 and has withdrawn that facility's establishment registration.

30. Another subsidiary of PHUSA, Philips North America LLC ("PNA"), is already the subject of a consent decree of permanent injunction. Following a series of violative inspections at PNA's facilities located at 3000 Minuteman Road, Andover, MA and 22100 Bothell Everett Highway, Bothell, WA, and the issuance of two Warning Letters, the government sought injunctive relief against PNA, which was doing business as Philips Medical Systems and Philips Healthcare. PNA's Andover and Bothell facilities are part of the Connected Care business segment. In 2017, PNA, without admitting or denying the allegations in the government's Complaint for Permanent Injunction, entered into a consent decree of permanent injunction designed to address the violations of the QS regulation at those facilities, primarily with respect to devices in its Emergency Care & Resuscitation business unit. *See* Consent Decree of Permanent Injunction, ECF No. 10, *U.S. v. Philips North America, LLC d/b/a Philips Medical Systems and Philips Healthcare*, 17-cv-11995-DJC (D. Mass. Oct. 31, 2017).

31. FDA has repeatedly warned Philips Respironics, Respironics California, and other subsidiaries of PHUSA about their violations of the Act and its implementing regulations and has emphasized the importance of compliance with the Act and its implementing regulations. Nevertheless, FDA's most recent inspections documented significant violations, many of which are the same as or similar to violations that have been previously observed at the Defendants' facilities.

32. Accordingly, based on the foregoing, unless restrained by order of this Court, Defendants will continue to violate 21 U.S.C. § 331(a) and (k).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing to be done any and all of the following acts:

A. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce, or causing the introduction or delivery for introduction into interstate commerce, any device that is adulterated within the meaning of 21 U.S.C. § 351(h);

B. violating 21 U.S.C. § 331(a), by introducing or delivering for introduction into interstate commerce or causing the introduction or delivery for introduction into interstate commerce, any device that is misbranded within the meaning of 21 U.S.C. § 352(t); and

C. violating 21 U.S.C. § 331(k), by causing devices to become adulterated within the meaning of 21 U.S.C. § 351(h) and/or misbranded within the meaning of 21 U.S.C. § 352(t), while such devices are held for sale after shipment of one or more of their components in interstate commerce.

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants and each of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them from manufacturing, processing, packing, labeling, holding, and distributing devices, as defined in 21 U.S.C. § 321(h), at or from their facilities located at 1001 and 1010 Murry Ridge Lane, Murrysville, PA; 312 Alvin Drive, New Kensington, PA; 174 Tech Center Drive, Mount Pleasant, PA; and 2271 Cosmos Ct., Carlsbad, CA—other than devices FDA determines to be medically necessary—

unless and until Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute devices are established, operated, and administered in compliance with 21 U.S.C. § 351(h) and 21 C.F.R. Part 820, and Defendants are in compliance with 21 U.S.C. § 360i(g) and 21 C.F.R. Part 806, in a manner that has been found acceptable to FDA.

III. Authorize FDA, pursuant to this injunction, to inspect Defendants' facilities to ensure continuing compliance with the terms of this injunction, with the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are performed.

IV. Order that Plaintiff be awarded costs and other such equitable relief as this Court deems just and proper.

Respectfully submitted,

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**Pro hac vice applications to be filed separately.*

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